Pharmaceutical Serialization: Track & Trace in the USA

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How do we implement Serialization?

Translating theory….

- Supply Chain Traceability across all echelons

- Hampering pharmaceutical counterfeiting efforts

- Discouraging drug theft

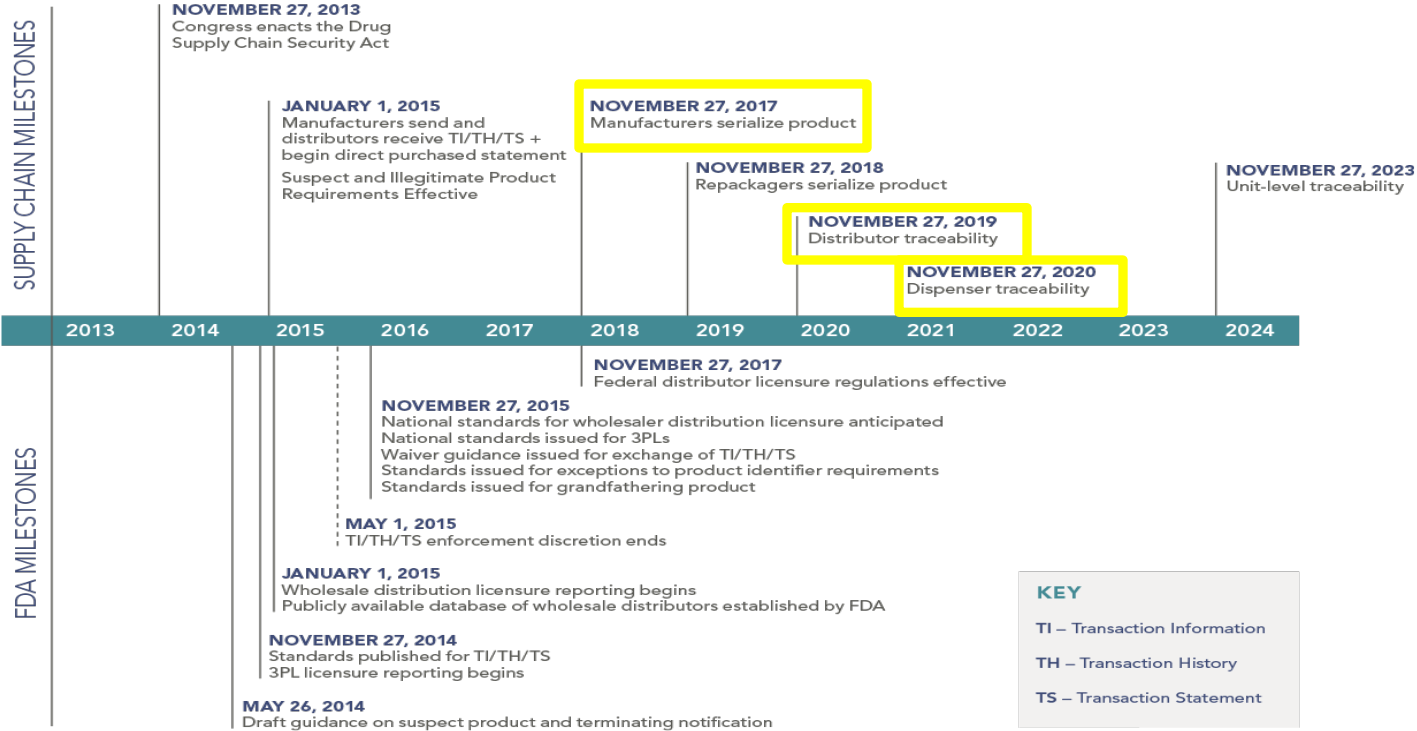- Improving visibility to source of vendor returned inventory

…to Reality

- Installation of necessary hardware and software

- Design processes to identify and seize counterfeits

- Incorporating loss-identification process into track & trace

- Adding the reverse supply chain to Serialization

DSCSA Timeline

FEDERAL IMPLEMENTATION TIMELINE

SUPPLY CHAIN MILESTONES

NOVEMBER 27, 2013
Congress enacts the Drug
Supply Chain Security Act

JANUARY 1, 2015
Manufacturers send and
distributors receive TI/TH/TS +
begin direct purchased statement

Suspect and Illegitimate Product
Requirements Effective

NOVEMBER 27, 2017
Manufacturers serialize product

NOVEMBER 27, 2018
Repackagers serialize product

NOVEMBER 27, 2019
Distributor traceability

NOVEMBER 27, 2020
Dispenser traceability

NOVEMBER 27, 2023
Unit-level traceability

2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024

FDA MILESTONES

NOVEMBER 27, 2017
Federal distributor licensure regulations effective

NOVEMBER 27, 2015
National standards for wholesaler distribution licensure anticipated
National standards issued for 3PLs
Waiver guidance issued for exchange of TI/TH/TS
Standards issued for exceptions to product identifier requirements
Standards issued for grandfathering product

MAY 1, 2015
TI/TH/TS enforcement discretion ends

JANUARY 1, 2015
Wholesale distribution licensure reporting begins
Publicly available database of wholesale distributors established by FDA

NOVEMBER 27, 2014
Standards published for TI/TH/TS
3PL licensure reporting begins

MAY 26, 2014
Draft guidance on suspect product and terminating notification

KEY

TI – Transaction Information

TH – Transaction History

TS – Transaction Statement

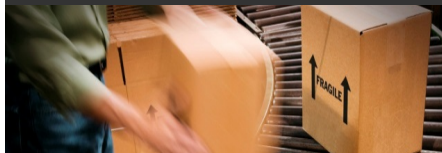# Manufacturer will set the baseline for future serialization

Manufacturers

- Nov 2017

- All Manufacturers need to place individual serialized code on their products

- Serial information needs to be stored in secured database

Distributors

- Nov 2019

- All Distributors will need to achieve 100% traceability of pharmaceuticals in their ownership

Dispensers

- Nov 2020

- All Dispensers will need to achieve 100% traceability of pharmaceuticals in their ownership

Success depends on overcoming the following challenges

Challenges	Description
Serialization Hardware	• The capital equipment necessary to print and scan the serialized labels needed for serialization – includes both unit level and aggregate level equipment
Serialization Database	• The database required to house all serialization data
TI/TH/TS Transmission	• The data capture and exchange process needed to ensure traceability across all supply chain echelons

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Compatibility of both hardware and software need validated

Challenges	Potential Roadblocks		Decision Needed
Serialization Hardware	• Lack of compatibility with existing line equipment • Insufficient speed/robustness to maintain output • Installation difficulties		• Specification of necessary hardware capabilities • Standardization of installation process
Serialization Database	• Robustness of database under heavy load • Data Security • Data Integrity		• Specification of database size, scalability, security • Codification of data management processes
TI/TH/TS Transmission	• Capture of necessary transaction information • Transfer of transaction information		• Codification of best practices to ensure reliable capture and transmission of data

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Distributor will extend serialization capabilities

Manufacturers	Distributors	Dispensers
• Nov 2017	• Nov 2019	• Nov 2020
• All Manufacturers need to place individual serialized code on their products	• All Distributors will need to achieve 100% traceability of pharmaceuticals in their ownership	• All Dispensers will need to achieve 100% traceability of pharmaceuticals in their ownership
• Serial information needs to be stored in secured database		

Success depends on overcoming the following challenges

Challenges	Description
TI/TH/TS Transmission	• The data capture and exchange process needed to ensure traceability across all supply chain echelons
Data disaggregation and aggregation	• The ability for Distributors to disaggregate high level serialization information into unit-level, and vice versa
Serialization Data Manipulation	• The ability for Distributors to manipulate serialization data in the master database regardless of database ownership

Reliability of data exchange is of highest importance

Challenges	Potential Roadblocks	Decision Needed
TI/TH/TS Transmission	• Capture of necessary transaction information • Successful transfer of transaction information	• Codification of best practices to ensure reliable capture and transmission of data
Data disaggregation and aggregation	• Efficient and timely disaggregation of linked-pedigree data • Ability to re-aggregate serialized units for shipment	• Codification of data disaggregation and aggregation processes • Standardization of receiving and shipping processes to enable data disagg./agg. process
Serialization Data Manipulation	• Ability to edit and manipulate serialized database if needed	• Codification of best practices to ensure reliable editing of data

Dispensers will build on existing serialization framework

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Distributors

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Dispensers

- Nov 2020

- All Dispensers will need to achieve 100% traceability of pharmaceuticals in their ownership

Success depends on overcoming the following challenges

Challenges	Description
TI/TH/TS Transmission	• The data capture and exchange process needed to ensure traceability across all supply chain echelons
Data disaggregation	• The ability for Dispensers to disaggregate high level serialization information into unit-level

Dispenser stage will test system-wide serialization robustness

Challenges	Potential Roadblocks	Decision Needed
TI/TH/TS Transmission	• Capture of necessary transaction information • Successful transfer of transaction information	• Codification of best practices to ensure reliable capture and transmission of transaction data
Data disaggregation	• Efficient and timely disaggregation of linked-pedigree serialized data to keep pace with operations	• Standardization of receiving & sales processes to enable data disaggregation process

Key Tasks for Implementation

Specify hardware capability and compatibility with existing equipment

Ensure robust & secure serialization database in place

Introduce unified TI/TH/TS data exchange process to ensure reliability

Further specification of DSCSA requirements is key to implementation success

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APPENDIX

Industry prep

- Outline the differences between old and new process, one-time and ongoing costs difference.
- What will your standard information system architecture look like for hardware and software?
- Have you accounted for backup and recovery capability? Are you engaged with cloud capability or local servers?
- How have you interpreted the standards for interoperable data exchange, and the legislative and regulatory requirements, and are they consistent with everyone in your supply chain?
- Have you coordinated with all of your trading partners and your CMOs?
- What are your budgetary and schedule constraints?
- Do you have the resources available to implement your enterprise-wide program?
- How will serialization impact your line efficiency, operations, and distribution?
- Does your current label or carton artwork accommodate the area required for printing of serialized information?
- What is your interpretation for an aggregation strategy – DSCSA does not require it for 2017, but will downstream trading partners interpret it differently and/or require it to manage their business processes and/or be in compliance?
- How do you plan on handling rework/returns and exceptions?